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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,787	06/26/2001	Carl Nelson Skold		4399

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EXAMINER
DO, PENSEE T

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/891,787	Applicant(s) SKOLD, CARL NELSON	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cov r she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *20-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment( )

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-19, 52 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the five inventions listed are all parts of a single invention and can be examined together as a single invention without undue burden. This is not found persuasive because of reasons explained in the previous restriction requirement. Inventions I and II cannot be examined together because they are drawn to two different categories and would require two separate searches. The same reason applies for groups III-V.

The requirement is still deemed proper and is therefore made FINAL.

Claim Status

Claims 1-19, 52 are being examined. Claims 20-51 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-19, 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because, as recited, the magnetizable particles have a coupling group having an affinity for the target material. It is unclear how the coupling group is attached to the magnetizable particles since the magnetizable particles have a

coating of polysaccharide derivative having a pendant functional group. Does the couple group attach to the functional group?

Claim 1, line 6, a word is missing after "particles" first occurrence. Please correct.

Claim 14 is indefinite. In line 4, the recitation of "such as" is unclear if the halide or sulfonate is merely exemplary or limiting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 9, 11, 14, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Molday (US 4,452,773).

Molday teaches a method of separating a target material from a suspension or dispersion, said method comprising the steps of: combining magnetizable particles composed of magnetic iron oxide coated with a polysaccharide, preferably dextran, or a derivative thereof having pendant functional groups with a suspension containing target material for said target material to bind to said magnetizable particles; and applying a magnetic field to said suspension or dispersion to separate the magnetizable particles and target material. The target material is a biological material. The magnetic particles have a particle size of about 100 to 700 Angstrom. (see col. 3, lines 14-22). The purified complex of magnetizable particles bound to said target material is dissociated and said magnetic particles are removed by magnetic means to provide substantially pure

preparation of said target material. (see col. 4, lines 31-38). The magnetizable metal oxide is an iron oxide (see col. 3, lines 1-2). The magnetizable particles are produced by treating with a base- NH4OH. (see col. 8, lines 38-40). The pendant functional group of the polysaccharide is an aldehyde group (see col. 54-56). The polysaccharide is dextran. (see col. 4, lines 10-50). Molday teaches the same method for making particles as in Example 1 of the specification of the present invention. The method comprises preparing a solution by diluting ferric chloride and ferrous chloride tetrahydrate were added dropwise with agitation over a period to a solution containing concentrated ammonium hydroxide in a water bath. Aggregates were removed by 3 cycles of centrifugation in a low-speed clinical centrifuge for 5 minutes. The ferromagnetic iron-dextran particles were separated from unbound dextran by gel filtration chromatography. Five milliliters of the reaction mixture were applied to a 2.5 X 33 cm column and eluted with sodium acetate, sodium chloride. The purified ferromagnetic iron-dextran particles were collected. Since Molday teaches the same method of making colloidal aggregates of magnetizable iron oxide particles, Molday's magnetizable particles are formed of particles of crystallites of magnetizable metal oxide. (see col. 8, lines 31-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6-8 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molday (US 4,452,773) further in view of Chagnon et al. (US 4,628,037).

Molday has been discussed above.

However, Molday fails to teach that the magnetizable particles are formed of particles of crystallites of a magnetizable metal oxide; and a mass of crystallites having a particles size of about 3 nm to about 25 nm. Molday also fails to teach that the crystallites of the magnetizable metal oxide includes a coating of an organosilane bonded directly to the particles of the crystallites and wherein said coating of polysaccharide derivative is bonded to said organosilane. Molday fails to teach a kit comprising the components for performing the method of claim 1.

Chagnon teaches magnetic particles useful in biological applications involving the separation of molecules. The magnetic particles has a metal oxide core composed of a cluster of ferromagnetic crystals of an iron oxide. (see col. 7, lines 22-30). The ferromagnetism is defined as that magnetic behavior exhibited by iron oxides with crystal size greater than about 500 Angstrom. The method of preparing the magnetic particles comprise precipitating metal salts in a base to form fine magnetic metal oxide crystals, redispersing, washing the crystals in water and in an electrolyte. The magnetic particles comprise a magnetic metal oxide core generally surrounded by an adsorptively or covalently bound organosilane coat to which a wide variety of bioaffinity adsorbents can be covalently bonded through selected coupling chemistries. The coupling chemistries include gluteraldehyde couplings; carbodimide, diazotization. (see col. 9, lines 3-12).

It would have been obvious to one of ordinary skills in the art to use clusters of ferromagnetic crystals of an iron oxide as taught by Chagnon in the method of producing the magnetic particles discussed by Molday since Molday's particles derived from iron oxide. Furthermore, it would have been obvious to one of ordinary skills in the art to add to the organosilane coating as taught by Chagnon the polysaccharide coating as taught by Molday because the hydroxyl group in polysaccharide forms a stable bond directly to the silane group. Regarding claim 52, it would have been obvious to one of ordinary skills in the art to produce a kit comprising the components for performing the combined method of Molday and Chagnon for economic convenience.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molday in view of Niswender (US 4,048,298).

Molday has been discussed above.

However, Molday fails to teach the pendant functional group of polysaccharide is a carboxyl group attached to polysaccharide through a linker having at least one heteroatom for every three-carbon atom in the linker; the heteroatom is Oxygen; the linker is derived from ethylene glycol, an oligoethylene glycol or a polyethylene glycol.

Niswender teaches a polymeric carrier with a suitable reactive group. The reactive groups are carboxyl, hydroxyl and primary or secondary amine groups. The polymeric material is polysaccharides, dextrin. The reactive group can be crosslinked by inclusion of a substantial amount of a polyethylenically unsaturated monomer, such as ethylene glycol dimethacrylate.(see col. 4, lines 5-45).

It would have been obvious to one of ordinary skills in the art to attach carboxyl group to polysaccharide via an ethylene glycol linker as taught by Niswender to form a polymeric coating on the magnetizable particles of Molday since these polymeric coatings are used for attaching ligands/antibody to detect target analyte in assay.

Remarks

Claims 10, 12, 18 are free of prior arts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Pensee T. Do
Patent Examiner
July 24, 2003

FORM PTO-1472
(Rev. 4-2002)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

EXAMINER'S CASE ACTION WORKSHEET

Application No. 09/891,787		Legal Instrument Examiner

CHECK TYPE OF ACTION

DATE OF COUNT

☒ Non-Final Rejection	☐ Restriction/Election Only	☐ Final Rejection
☐ Ex Parte Quayle	☐ Allowance	☐ Advisory Action
☐ Examiner's Answer	☐ Reply Brief Noted	☐ Non-Entry of Reply Brief
☐ Defective Notice of Appeal	☐ Interference Disposal SPE _____ (Approval for Disposal)	☐ Suspension (Examiner-Initiated) SPE _____ *(initial)*
☐ Defective Appeal Brief	☐ SIR Disposal (use only after FAOM)	☐ Supplemental Examiner's Amendment
☐ Miscellaneous Office Letter (With Shortened Statutory Period Set)	☐ Notice of Non-Responsive Amendment (With One Month Time Period set)	☐ Miscellaneous Office Letter (No Response Period Set)
☐ Abandonment after BPAI Decision	☐ Supplemental Action (excluding Examiner's Answer)	☐ Response to Rule 312 Amendment
☐ Letter Restarting Period for Response (e.g., Missing References)	☐ Interview Summary	☐ Authorization to Change Previous Office Action SPE: _____ *(Initial)*
☐ Abandonment	☐ Express Abandonment Date: _____	☐ Other Specify: _____

Examiner's Name: Pensee T. Do **AU:** 1641